

REMARKS

Claims 55-91 were pending in this application. Claims 55-91 have been canceled. New claims 92-100 have been added. Support for new claims can be found throughout the specification and the claims as filed, in particular at page 17, lines 9-11, and lines 22-26, and page 9, lines 15-16. No new matter has been added. Applicant reserves the right to file a divisional application for the non-elected claims or to reinstate certain claims.

Amendment of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to more particularly point out and distinctly claim the invention to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Applicants respectfully traverse the Examiner's rejections and request reconsideration of the application in view of the amendments made above and the remarks that follow.

The Invention

Applicant's invention provides a device that optimally delivers a therapeutic agent to a tissue using ultrasound energy, without causing disruption of the tissue. In addition, Applicants use ultrasound frequencies of *greater than about 500 kHz and less than or equal to about 3MHz, whereby the frequency promotes the therapeutic effect of the therapeutic agent.* This high frequency ultrasound energy, along with a *duty cycle greater than about 10%* provides a simple delivery device that "promote[s] the therapeutic effect of topically applied agents." (See page 9, lines 15-16, and page 18, line 13). Moreover, the tissue does not require any treatment, such as treatment that creates micropores, prior to using the device.

Drawings

Figure 10 has been corrected as suggested by the Examiner to include the traversal cut with all other corrections.

Rejection of Claim 91 under 35 USC § 112, First paragraph

Claim 91 has been rejected under § 112, first paragraph as containing subject matter which was not described in the specification in such a way to convey that the inventor had possession of the claimed invention. In particular, because the therapeutic agents of claim 91 “are disclosed for hair loss and not for penile tissue.”

Applicants thank the Examiner for pointing out this inconsistency. However, Applicant has canceled claim 91, thereby rendering the rejection moot.

Rejection of Claims under 35 USC § 102

Claims 64, 66, 67, 79, 80, 81, 82, 84-88 have been rejected under 35 U.S.C. 102(a) as being anticipated by Eppstein (US 6,527,716). In particular, the Office action asserts that:

Eppstein discloses a therapeutic drug delivery device (Fig. 28) including an applicator, an ultrasound transducer, a controller for varying the frequency and power of the ultrasound energy, and a detector for monitoring feedback signals from the transducer (col. 41, and 54). The intended use has not been given patentable weight.

Claims 67 and 82 (and dependent claims thereof) have been canceled, thereby rendering the rejection moot with regard to these claims.

Rejection of Claims under 35 USC § 102

Claims 64, 66, 67, 79, 80, 81, 89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Henley (US 5,538,503). In particular, the Office Action asserts that:

Henley discloses a therapeutic drug delivery device including an applicator 10, an ultrasound transducer 11, a controller for varying the frequency and power of the ultrasound energy, and a detector for monitoring feedback signals from the transducer and 54). The intended use has not been given patentable weight. The device can deliver several kind of drugs i.e. minoxidil.

Claims 67 (and dependent claims thereof) have been canceled, thereby rendering the rejection moot with regard to these claims.

Rejection of Claims under 35 USC § 102

Claims 64, and 79-83, and 85-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogden (US 5,656,016). In particular, the Office Action asserts that:

Ogden discloses a therapeutic drug delivery device comprising an applicator 12, an ultrasound transducer, and a detector for monitoring feedback signals from the transducer (col. 4, lines 17-23). The intended use has not been given patentable weight, since the device can be used in other parts of the body.

Claims 64 (and dependent claims thereof) have been canceled, thereby rendering the rejection moot with regard to these claims.

Rejection of Claims under 35 USC § 102

Claims 64, 66, 67, 80, and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by Bock (US 5,618,275). In particular, the Office Action asserts that:

Bock discloses an ultrasonic device having an applicator, 1, 2, 3 and an ultrasound transducer. The intended use has not been given patentable weight.

Claims 64 (and dependent claims thereof) have been canceled, thereby rendering the rejection moot with regard to these claims.

Rejection of Claims under 35 USC § 103

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (US 5,538,503) in view of Neal (US 6,103,765). In particular, the Office Action asserts that:

Henley's device can deliver several kind of drugs i.e. minoxidil. However, Henley fails to disclose the use of specifically a phosphodiesterase type-5 inhibitor such as sildenafil or alprostadil. Neal teaches the use of sildenafil as a topical medicament. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Neal's sildenafil with Henley's device as an alternative way of topical drug delivery, since Henley is capable of delivering other drugs.

Applicant respectfully traverse the rejection. Claim 90 has been canceled, thereby rendering the rejection moot.

New Claims 93-100

New claims 92-100 have been added. Independent claim 92 is directed to a device for administration of topical therapeutic agents, comprising an applicator for applying an effective amount of a therapeutic agent to a tissue surface of a subject; and an ultrasound transducer, operatively coupled to the applicator, for providing ultrasound energy to the tissue surface at least one predetermined frequency to promote absorption of the agent through the tissue of the subject, wherein the ultrasound energy has a *duty cycle of greater than about 10%*, and wherein the ultrasound transducer further comprises at least one oscillating element capable of generating ultrasound energy at a *frequency of greater than about 500 kHz and less than or equal to about 3MHz, whereby the frequency promotes the therapeutic effect of the therapeutic agent.*

To address the Examiner's concerns with regard to the cited references, Applicant will address each reference separately.

Eppstein (US 5,538,503) discloses methods of creating pores in a membrane (i.e., poration) using various techniques, for example, puncturing the membrane with a microlancet, using laser energy, iontophoresis (*See* column 6, lines 6-47). The patent also describes the effect of laser light with dyes on pore formation (Example 8 and 9), as well as the effect of pre-chilling the skin (Example 10). The patent describes the use of "poration *together* with ultrasound" in Example 15 (Column 42). Thus, the teaching in Eppstein requires a two step process, whereby pores are first created, and then sonication may be used to deliver a therapeutic agent. Eppstein also repeatedly teaches the use of "low level ultrasound" (Column 42, lines 18), and that sonication using a low frequency region of "1kHz to 500kHz" should be used (*See* column 54, lines 17-18). However, fails to teach or suggest a "*frequency [that] promotes the therapeutic*

effect of the therapeutic agent” Thus, Eppstein does not teach each and every element, and thereby fails to anticipate the claimed invention.

With regard to Henley (US 5,538,503), this patent describes methods for iontophoretic delivery of medication with, or without ultrasonic vibration. The ultrasound methods described by Henley rely on using low frequency sonication. Henley does not teach, or suggest using high frequency sonication with a frequency *greater than about 500 kHz and less than or equal to about 3MHz, whereby the frequency promotes the therapeutic effect of the therapeutic agent*. Moreover, Henley is completely silent about a duty cycle, let alone a duty cycle *of greater than about 10%*. Accordingly, Henley fails to anticipate the claimed invention.

With regard to Ogden (US 5,656,016), this patent is silent about using a *frequency promotes the therapeutic effect of the therapeutic agent* and a *duty cycle greater than about 10%*. Thus, Ogden fails to anticipate the claimed invention.

With regard to Bock (US 5,618,275), this patent only describes using low frequency sonication of “15kHz to 25kHz.” There is no teaching or suggestion for using a frequency *greater than about 500 kHz and less than or equal to about 3MHz, whereby the frequency promotes the therapeutic effect of the therapeutic agent*. Moreover, the patent is silent with respect to using a duty cycle, let alone a *duty cycle greater than about 10%*. Accordingly, Bock fails to anticipate the claimed invention.

With regard to Neal (US 6,103,765), this patent simply describes various pharmaceutical compositions that can be used for treating male erectile dysfunction. There is no teaching or suggestion for using sonication, let alone sonication with a frequency *greater than about 500 kHz and less than or equal to about 3MHz, whereby the frequency promotes the therapeutic effect of the therapeutic agent*. The patent is also completely silent about using a duty cycle, let alone a *duty cycle greater than about 10%*. Accordingly, Neal fails to anticipate the claimed invention.

Moreover, the combination of references fails to teach or suggest the claimed invention because none of the references describe a device in which the sonication frequency is greater than about 500 kHz and less than or equal to about 3MHz, *whereby the frequency promotes the therapeutic effect of the therapeutic agent*. Thus, the skilled artisan would not be motivated to use either reference alone, or in combination to arrive at the claimed invention.

For all the foregoing reasons, the Examiner is respectfully requested to withdraw the rejections.

CONCLUSION

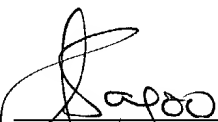
In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. The Examiner is urged to telephone the undersigned Applicant's Representative in the event that such communication is deemed to expedite prosecution of this matter.

Respectfully submitted,

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